IUCLID

for pesticides

WHY IT WAS IMPLEMENTED AND HOW IT WILL BE USED

ABIM 20TH OCTOBER 2020

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IUCLID (Internation Uniform Chemical Information database)

- IUCLID was implemented in 1993 as a software application to capture, store, maintain and exchange data on intrinsic and hazard properties on chemical substances
- Hosted by ECHA (European Chemicals Agency) in collaboration with OECD

Source: ECHA

IUCLID – key drivers

EFSA Matrix project

- Transparent evidence management and **structured data** to support the scientificassessment

One substance – one hazard assessment

- Aligment of REACH, CLP and agrochemical assessment

Transparency Regulation

- Amendment of article 39f of General Foodlaw calling EFSA to define standard data formats

IUCLID implementation milestones

efsa
European Food Safety Authority

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

EFSA Technical Group on PESTICIDES – IUCLID pilot

IUCLID Pilot (and beyond)

- Started in November 2019 commenced in April 2020
- Technical Working Group still active today
- Partcipants from all stakeholders:
  - Applicants: IBMA, ECPA, ECCA
  - Competent MS authorities: France, Germany, Finnland, Portugal, Austria
  - EFSA
  - COM
- POC Dossiers for chemical active substance and microorganism (353 issues identified)
- Continous work on improving the system (e.G. 16 endpoint study records change requests for microorganisms)
- Currently ongoing: Testing of IUCLID 6.5

IUCLID legal implementation

- **For renewals**: Draft Renewal Regulation for voting in October 22/23 ScoPAFF containing article 7 for mandatory IUCLID submission
- **For new approvals**: First discussion in ScoPAFF
- **For MRLs**: ?
- **For national product authorisations**: IUCLID not foreseen at this stage

Article 7

Format and software for the submission of the application for renewal

. The Authority shall establish and make available online a central submission system. The Authority shall ensure that the central submission system facilitates the verification of admissibility performed by Member States in accordance with Article 8.

. The standard data formats proposed by the Authority as part of the IUCLID software package pursuant to Article 39f of Regulation (EC) No 178/2002 are hereby adopted.

. The application for renewal shall be submitted via the central submission system using the IUCLID software package.

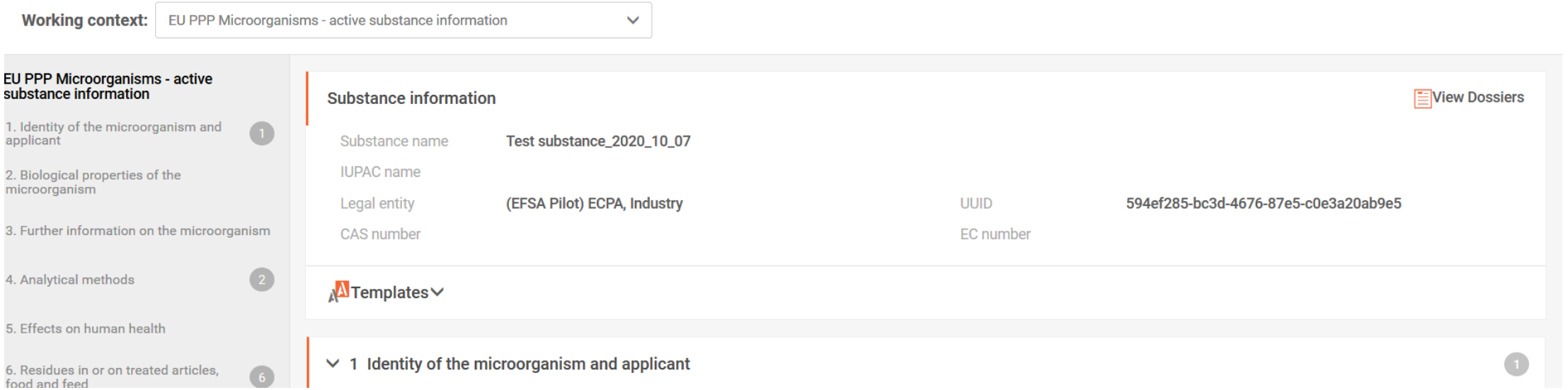
. The applicant, when requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, shall indicate such information using the relevant IUCLID functionality.

IUCLID general setup

IUCLID consists of data for substances and mixtures linked to a Legal entity

All data objects can be uniquely identified by a UUID

Data can be sorted according to different legistlations by Working context

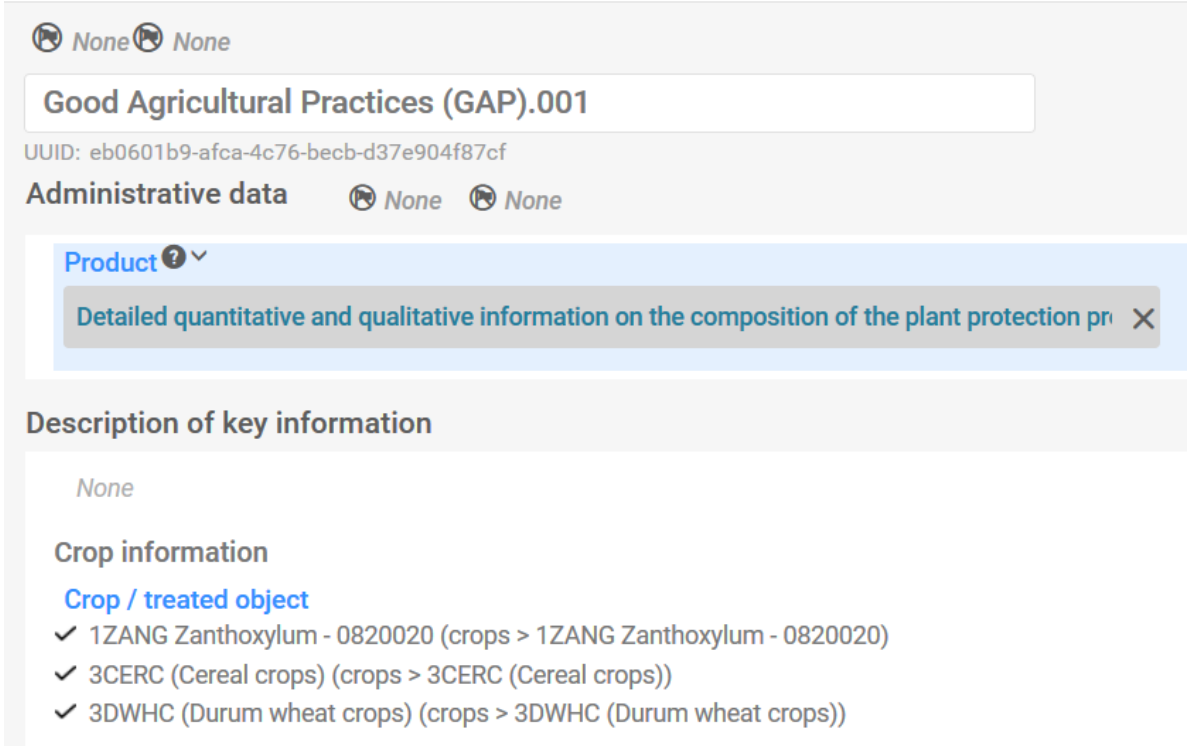


IUCLID general setup

Data can be entered into:

- Endpoint summary documents
- Study summary documents (OECD Harmonised Templates),
- Domain specific documents

for the substance (microorganism) and the mixture

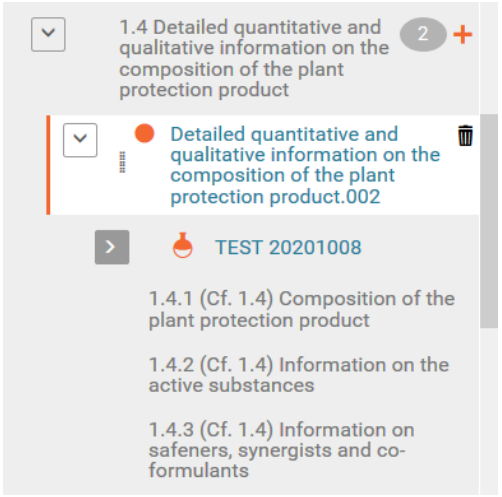


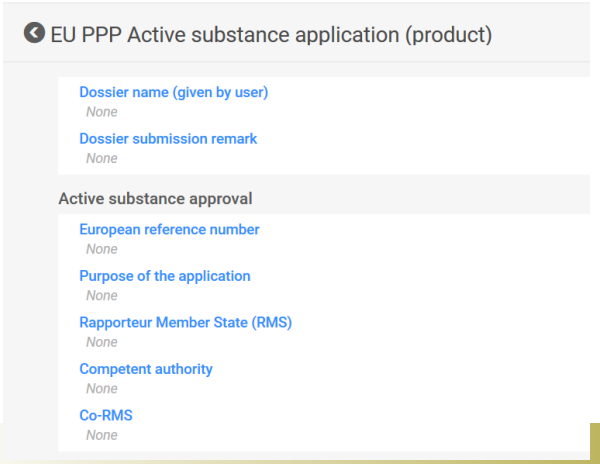
IUCLID Dossier compilation

All components of the assessment entity need to be linked within the mixture (representative product)

Dossier representing a snapshot of the relevant data at a time

Dossier will have to be compiled from the representative product and submitted to EFSA instance of ECHA Cloud

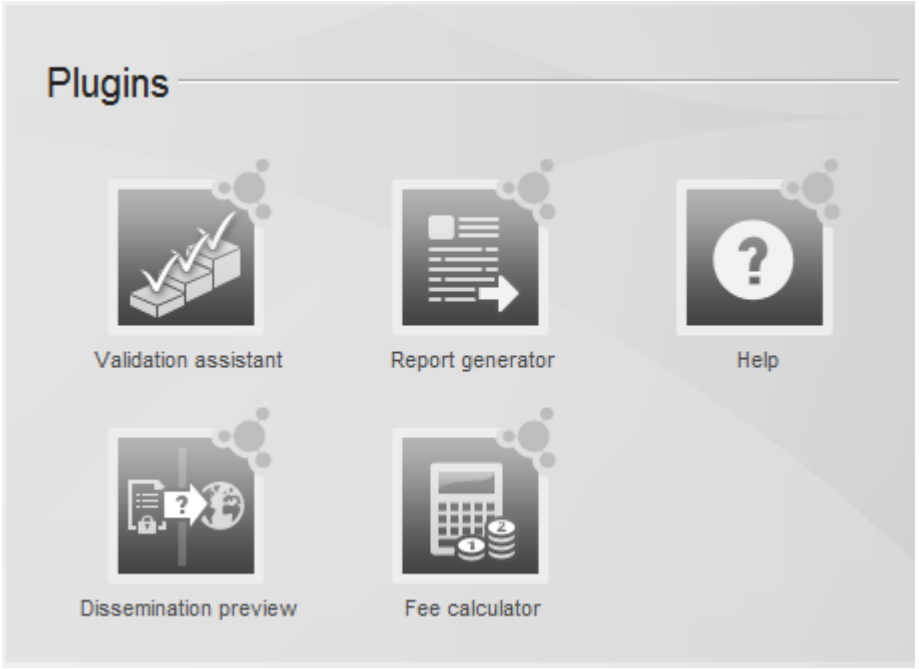




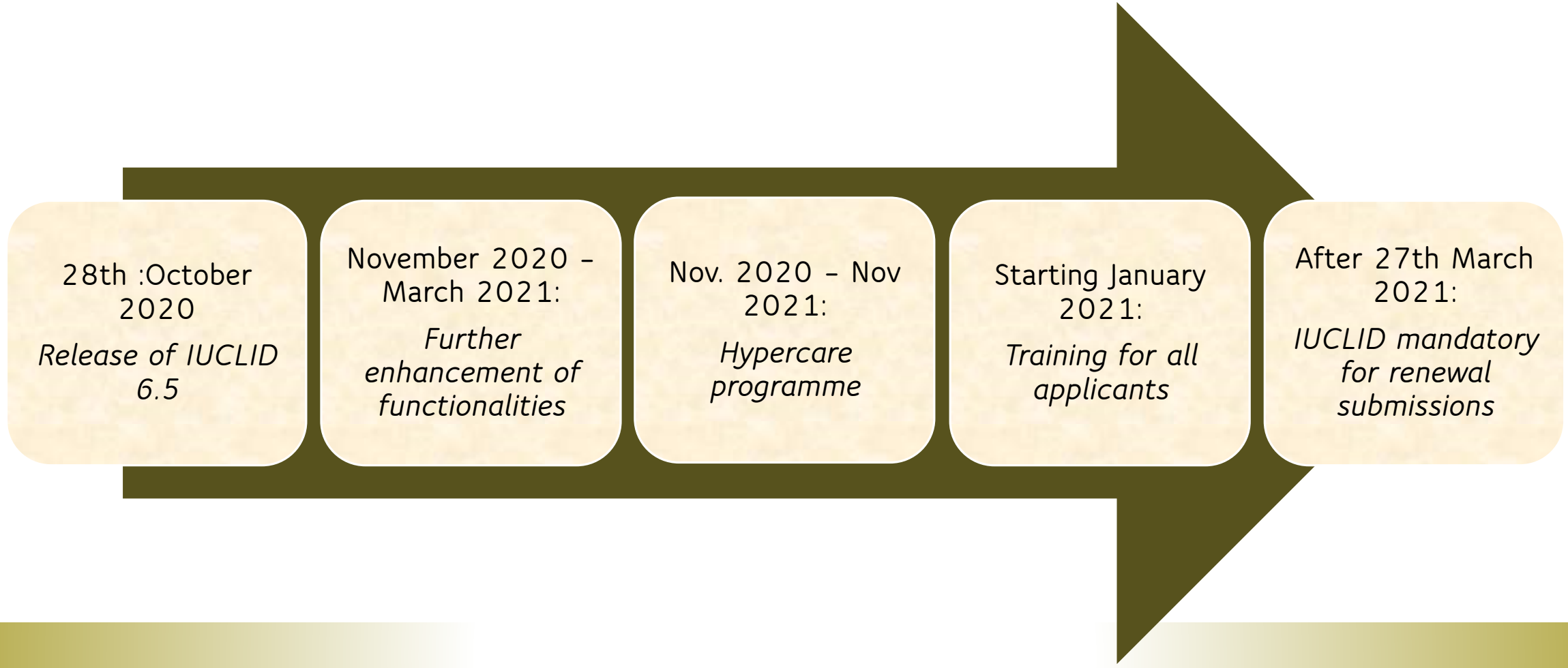
IUCLID Evaluation process

Several features implemented or to be implemented to support the evaluation proces:

- Validation rules to perform a Completeness Check
- Annotations to be used for communication between evaluator and applicant
- Reporting functionalities for automation of LOEP, Reference Lists, DAR or RAR (future Vision)
- Dissemination tool for publication



IUCLID implementation steps



IUCLID challenges for applicants

- Insufficient OHTs (designed for chemical evaluation)
- Missing OHTs and documents (for higher tier studies, Risk assessments etc.)
- **Traditional summary Dossier (Document M) still required to ease evaluation process**

  - Significant increase of workload for applicants
  - Significant change management needed for Dossier generation process
  - Further Delays in the evaluation process can be expected

!Even more severe for microorganisms!

Thank You

Time for Questions ?